



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/038,894	03/11/98	STOUGHTON	R 24730-2202

HM22/0320  
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EXAMINER

MELLER, M

ART UNIT

PAPER NUMBER

1651

13

DATE MAILED: 03/20/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/038,894

Applicant(s)

Stoughton et al.

Examiner

Michael Meller

Group Art Unit

1651



☒ Responsive to communication(s) filed on Dec 27, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-36 and 38-40 is/are pending in the application.

Of the above, claim(s) 1-18, 25-36, and 38-40 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 19-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8, 10

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Specification***

1. A substitute specification is required pursuant to 37 CFR 1.125(a) because applicant's amendment filed 11/2/99 has far too many amendments for the examiner to consider and enter into the instant specification.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

### ***Election/Restriction***

Applicant's election of species by Stephanie Seidman on 3/6/2000 of Futhan (6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is noted. The requirement for the election of a disorder is dropped.

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***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 19 claims, "A method of treating or preventing disorders...", such language is not enabled by the instant specification. Such language requires undue experimentation for one of ordinary skill in the art to test to see if the protease inhibitor actually "prevents" such a disorder. The Patent Office is not equipped to test such compounds as a protease inhibitors on any and all disorders to see if they will "prevent" it. Such a claim is tantamount to a cure which has a very high standard for enablement. Applicant must show evidence on the record that they have tested the many protease inhibitors on many different disorders.

The instant claims encompass a method which employs any protease inhibitor which inhibits any disorder. However, the instant specification only describes a single protease inhibitor which supposedly inhibits any and all disorders. One does not have a reasonable expectation that any and all disorders can be prevented by using these protease inhibitors. To practice the claimed

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method with any and all protease inhibitors would require one to first make the substantial inventive contribution of discovering the specific disorder that is inhibited by the specific protease inhibitor.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 19-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Okada et al.(Journal of International Medical Research, 1991, Vol. 19, pgs, 348-350), Okada et al.(Journal of International Medical Research, 1991, Vol. 19, pgs, 234-236, Yanamoto et al. or Yonekura et al.

Applicant is claiming a method of treating or preventing disorders using a protease inhibitor.

Applicant elected the protease inhibitor, Futhan.

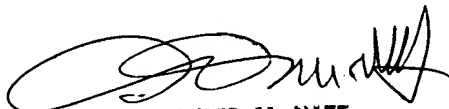
The references each teach Futhan, also known as nafamostat mesylate and FUT-175 to treat diabetes, disseminated intravascular coagulation and cerebral infraction, see abstracts.

The references may not specifically state that the amount of nafamostat mesylate or FUT-175 they used lowered cell activation, but this limitation is inherent in the references since they do treat patients with the protease inhibitor and get very positive results.

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No claim is allowed.

Any inquiries concerning this communication should be directed to Examiner Mike Meller at telephone number (703) 308-4230. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Fax phone number for the art unit is (703) 308- 0294. Any inquiries of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128151